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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/767,421	01/22/2001	Michael J. Shamblott	JHU1750-1	9551

7590 02/15/2007
LISA A. HAILE, Ph.D.
GRAY CARY WARE & FREIDENRICH LLP
Suite 1100
4365 Executive Drive
San Diego, CA 92121-2133

EXAMINER

CROUCH, DEBORAH

ART UNIT	PAPER NUMBER
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1632

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 09/767,421	Applicant(s) SHAMBLOTT ET AL.	
	Examiner Deborah Crouch, Ph.D.	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6,9-13,15,22-32 and 34-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6,9-13,15,22-32 and 34-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on January 22, 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The finality of the office action mailed June 12, 2006 is removed.

Applicant's arguments filed January 16, 2006 have been fully considered but they are not persuasive. The amendment has been entered. Claims 1, 9-13, 15, 6, 22-32 and 34-38 are pending.

Should the phrase, "lacking telomerase activity" be removed from the claims, the art rejections of the previous office actions, or ones similar to them will be made.

The term "EBD-derived cell" means an undifferentiated cell that composes an embryoid body.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 9-13, 15, 16, 22-32 and 34-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 22 and 38 contain language not supported by the specification. The claims state "adhesion to a defined substrate lacking a feeder layer" and "lacking telomerase activity." A review of the specification, with emphasis on the particular paragraphs indicated by applicant does not convey that at the time of the present invention, applicant had possession of the claimed invention.

The specification discloses growth of embryoid body cells on a substrate in the absence of feeder cells, but makes no reference to the substrate being "defined"

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(specification, page 53, lines 8-10). The closest mention of "defined" with regards to the culture of EBD cells is "defined extracellular matrix components" (page 22, lines 20-23). With regard to telomerase activity the specification clear states the embryoid body derived cells express telomerase activity (specification, page 21, lines 7-8). It is suggested that applicant delete "defined" and the phrase "lacking telomerase activity."

Claims 1, 9-13, 15, 6, 22-32 and 34-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not enable a use for EBD cells lacking telomerase activity that is senescent cells. The uses disclosed in the specification each require the cells to actively divide. Senescent cells are not going to be useful for cell culture, tissue transplantation, tissue engineering, drug discovery or gene therapy. A senescent cell has quit dividing. Each disclosed use requires that the cells divide.

The culture conditions for the EDB cells are all nonpermissive for the growth of hEGCs, that is in the absence of LIF and the absence of a feeder layer (specification, page 65-66). Further, claims 1, 11, 22 and 30 state the EBD cells proliferate under suitable conditions that are nonpermissive for proliferation of hEGCs. The only culture conditions enabled by the specification that are nonpermissive for the proliferation of hEGCs is culture in media that lacks leukemia inhibitory factor and a fibroblast feeder layer. The claims should be so limited.

Thus at the time of the instant invention, the skilled artisan would have needed to engage in an undue amount of experimentation to make and use the invention as claimed.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 9-13, 15, 6, 22-32 and 34-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are directed to EBD cells, which lack telomerase activity or senescent EBD cells. This is confusing because the specification teaches cells undergoing more than 70 population doubling, clearly an indicator of telomerase activity (page 64, lines 16-18.) From the disclosure as a whole, the invention does not seem to senescent cells, but cells that are embryonic and proliferative.

The claims are free of the prior art. At the time of the instant invention, the prior did not teach or suggest a human EBD that lacked telomerase activity.

It is noted that Hogan, of record, teaches human EBD cells and methods of making them. However, Hogan's cells are actively dividing. Should applicant amend the claims, deleting "lacking telomerase" activity, the Hogan reference or other references will be used to reject the claims under 35 U.S.C. § 102, 103 or 102/103. At this point, the only claims potentially available to applicant would be methods of obtaining EBD cells if the claims were appropriately limited away from Hogan. The human EBD cells of Hogan are seen as anticipating the presently claimed cells. The examiner has no suggestions at this point to forward the cell claims to allowance.

As always, applicant's representative is invited to call the examiner to discuss the rejections present or past so that resolution can be obtained.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Fri, 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Deborah Crouch, Ph.D.
Primary Examiner
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February 9, 2007